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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

PAUL GRANT MACAULEY and ARLENE
DORIS MACAULY,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-3458-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE, LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
 3 ("Searle") (collectively "Defendants"), and file this Answer to Plaintiffs' Complaint
 4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
 8 Bextra® (valdecixib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
 9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
 10 periods in which Plaintiff was prescribed and used Bextra®.

11 **II.**

12 **ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
 15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
 16 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
 17 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
 18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
 19 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
 20 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
 21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 22 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
 23 with its FDA-approved prescribing information. Defendants state that the potential effects of
 24 Bextra® were and are adequately described in its FDA-approved prescribing information,
 25 which was at all times adequate and comported with applicable standards of care and law.
 26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
 27 and deny the remaining allegations in this paragraph of the Complaint.

28 2. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
2 Defendants are without knowledge or information sufficient to form a belief as to the truth of
3 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,
4 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
5 Complaint.

6 3. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same.
8 Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining
9 allegations in this paragraph of the Complaint.

10 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of
11 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
12 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
13 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
14 Bextra® in the United States, including California, to be prescribed by healthcare providers
15 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
16 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
17 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
18 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
19 this paragraph of the Complaint.

20 5. Defendants admit that Searle is a Delaware limited liability company with its principal
21 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®
22 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
23 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 deny the remaining allegations in this paragraph of the Complaint.

26 6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
27 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
28 marketed and co-promoted Bextra® in the United States, including California, to be prescribed

1 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
2 approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in
3 interest" are vague and ambiguous. Defendants are without knowledge or information to form
4 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the
5 remaining allegations in this Paragraph of the Complaint.

6 7. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
11 the allegations in this paragraph of the Complaint.

12 8. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
13 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
14 the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining
15 allegations in this Paragraph of the Complaint.

16 **Response to Allegations Regarding Jurisdiction and Venue**

17 9. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
19 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
20 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
21 exclusive of interests and costs.

22 10. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
24 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny
25 committing a tort in the State of Oregon or the State of California and deny the remaining
26 allegations in this paragraph of the Complaint.

27 11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Bextra® in the United States, including California and Oregon, to be

1 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
2 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
3 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
4 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
5 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that they provided FDA-approved prescribing information regarding Bextra®.
7 Defendants admit that they do business in the States of Oregon and California. Defendants
8 state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
9 Defendants are without knowledge or information to form a belief as to the truth of such
10 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
11 remaining allegations in this paragraph of the Complaint.

12 **Response to Allegations Regarding Interdistrict Assignment**

13 12. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is required. To the extent that a response is deemed required, Defendants
15 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
16 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
17 Panel on Multidistrict Litigation on September 6, 2005.

18 **Response to Factual Allegations**

19 13. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
20 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe
21 and effective when used in accordance with its FDA-approved prescribing information.
22 Defendants state that the potential effects of Bextra® were and are adequately described in its
23 FDA-approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 14. The allegations in this paragraph of the Complaint are not directed toward Defendants
27 and, therefore, no response is required. To the extent a response is deemed required,
28 Defendants state that Plaintiff fails to provide the proper context for the allegations in this

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1 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
2 form a belief as to the truth of such allegations and, therefore, deny the same.

3 15. The allegations in this paragraph of the Complaint are not directed toward Defendants
4 and, therefore, no response is required. To the extent a response is deemed required,
5 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
6 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
7 form a belief as to the truth of such allegations and, therefore, deny the same.

8 16. The allegations in this paragraph of the Complaint regarding “other pharmaceutical
9 companies” are not directed toward Defendants and, therefore, no response is required. To the
10 extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper
11 context for such allegations. Defendants therefore lack sufficient information or knowledge to
12 form a belief as to the truth of such allegations and, therefore, deny the same. Plaintiff fails to
13 provide the proper context for the remaining allegations in this paragraph of the Complaint.
14 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
15 such allegations and, therefore, deny the same.

16 17. The allegations in this paragraph of the Complaint are not directed toward Defendants
17 and, therefore, no response is required. To the extent a response is deemed required,
18 Defendants state that Plaintiff fails to provide the proper context for such allegations.
19 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
20 such allegations and, therefore, deny the same.

21 18. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
22 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
23 of such allegations and, therefore, deny the same.

24 19. Defendants state that Plaintiff’s allegations regarding “predecessors in interest” are
25 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
26 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
27 conduct and deny the remaining allegations in this paragraph of the Complaint.

28 20. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,

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1 Defendants admit that Celebrex® was launched in the United States in February 1999.
2 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
3 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
4 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
5 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
6 with their approval by the FDA. Defendants admit that, during certain periods of time,
7 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
8 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
9 providers who are by law authorized to prescribe drugs in accordance with their approval by the
10 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
11 directed toward Defendants and, therefore, no response is required. To the extent a response is
12 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
13 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
14 therefore lack sufficient information or knowledge to form a belief as to the truth of such
15 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 21. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
18 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
19 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
20 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
21 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
22 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
23 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
24 this paragraph of the Complaint.

25 22. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
26 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
27 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
28 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining

1 allegations in this paragraph of the Complaint.

2 23. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
3 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
4 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
5 the remaining allegations in this paragraph of the Complaint.

6 24. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
7 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
8 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
9 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
10 prescribing information. Defendants state that the potential effects of Bextra® were and are
11 adequately described in its FDA-approved prescribing information, which at all times was
12 adequate and comported with applicable standards of care and law. Defendants deny the
13 remaining allegations in this paragraph of the Complaint.

14 25. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which at all times was adequate and comported with applicable standards of care and law.
18 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
19 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
21 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
22 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
24 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
25 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
26 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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26. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

30. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to characterize the Talk Paper is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug approval meta-analysis study” in this paragraph of the Complaint. Defendants are without

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1 sufficient information to confirm or deny such allegations and, therefore, deny the same.
2 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
3 the study for its actual language and text. Any attempt to characterize the study is denied.
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 33. The allegations in this paragraph of the Complaint are not directed towards Defendants
6 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
7 state that the referenced article speaks for itself and respectfully refer the Court to the article for
8 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
9 the remaining allegations in this paragraph of the Complaint.

10 34. The allegations in this paragraph of the Complaint are not directed towards Defendants
11 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
12 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk
13 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the
14 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its
15 actual language and text. Any attempt to characterize the testimony is denied. Defendants
16 deny the remaining allegations in this paragraph of the Complaint.

17 35. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
19 deny the remaining allegations in this paragraph of the Complaint.

20 36. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
21 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
22 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
23 Defendants deny the remaining allegations in this paragraph of the Complaint.

24 37. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
25 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
26 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 38. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants deny the allegations in this
2 paragraph of the Complaint.

3 39. Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
6 paragraph of the Complaint.

7 40. The allegations in this paragraph of the Complaint are not directed towards Defendants
8 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
9 state that the referenced article speaks for itself and respectfully refer the Court to the article for
10 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
11 the remaining allegations in this paragraph of the Complaint.

12 41. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the allegations in this paragraph of the Complaint.

17 42. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
22 allegations in this paragraph of the Complaint.

23 43. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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1 44. Defendants deny the allegations in this paragraph of the Complaint.

2 45. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
3 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
6 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
7 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
8 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Bextra® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants are without knowledge or information
13 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used
14 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
15 allegations in this paragraph of the Complaint.

16 46. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
17 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
18 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
19 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
20 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
21 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
22 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Bextra® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28 47. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed

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1 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
2 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
3 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
4 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
5 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
6 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Bextra® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants admit, as indicated in the package insert
11 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
12 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
13 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 48. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which at all times was adequate and comported with applicable standards of care and law.
18 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
19 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
20 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
21 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

22 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
26 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
27 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
28 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Bextra® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 50. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which at all times was adequate and comported with applicable standards of care and law.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 51. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 52. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 53. Defendants deny the allegations in this paragraph of the Complaint.

24 54. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
25 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations
26 contained in this paragraph of the Complaint.

27 55. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 56. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 57. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 58. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
18 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
20 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
21 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
22 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
23 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 59. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
26 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
27 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
28 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,

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1 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
2 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
3 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 60. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
6 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
7 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
8 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
9 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
10 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
11 accordance with their approval by the FDA. Defendants admit, as indicated in the package
12 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
13 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
14 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining
15 allegations in this paragraph of the Complaint.

16 61. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants are without knowledge or information sufficient to form a belief as to the truth of
21 the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
23 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
24 Complaint.

25 62. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants are without knowledge or information sufficient to form a belief as to the truth of
2 the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the same.
3 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
4 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
5 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
6 that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the
7 remaining allegations in this paragraph of the Complaint.

8 63. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 64. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
13 Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this
16 paragraph of the Complaint.

17 65. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 66. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
22 Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this
25 paragraph of the Complaint.

26 67. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
28 Defendants state that Bextra® was and is safe and effective when used in accordance with its

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1 FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury
2 or damage and deny the remaining allegations in this paragraph of the Complaint.

3 68. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
5 Defendants admit that Bextra® was expected to reach consumers without substantial change in
6 the condition from the time of sale. Defendants deny the remaining allegations in this
7 paragraph of the Complaint.

8 69. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants state that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendants deny
14 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

15 70. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 **Response to First Cause of Action: Negligence**

18 71. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
19 Complaint as if fully set forth herein.

20 72. Defendants state that this paragraph of the Complaint contains legal contentions to
21 which no response is deemed required. To the extent a response is deemed required,
22 Defendants admit that they had duties as are imposed by law but deny having breached such
23 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 73. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 74. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants state that Bextra® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
10 were and are adequately described in its FDA-approved prescribing information, which was at
11 all times adequate and comported with applicable standards of care and law. Defendants deny
12 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
13 including all subparts.

14 75. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
19 deny the remaining allegations in this paragraph of the Complaint.

20 76. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants state that Bextra® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
24 were and are adequately described in its FDA-approved prescribing information, which was at
25 all times adequate and comported with applicable standards of care and law. Defendants deny
26 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 77. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 78. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 79. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 80. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants state that Bextra® was and is safe and effective when used in accordance with its
16 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
17 were and are adequately described in its FDA-approved prescribing information, which was at
18 all times adequate and comported with applicable standards of care and law. Defendants deny
19 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

20 81. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 82. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 83. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Second Cause of Action: Strict Products Liability – Failure to Warn**

27 84. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
28 Complaint as if fully set forth herein.

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1 85. Defendants state that this paragraph of the Complaint contains legal contentions to
2 which no response is deemed required. To the extent a response is deemed required,
3 Defendants admit that they had duties as are imposed by law but deny having breached such
4 duties. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
5 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
6 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
7 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
8 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
9 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
10 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Bextra® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny the remaining allegations in this
15 paragraph of the Complaint.

16 86. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants state that Bextra® was and is safe and effective when used in accordance with its
19 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
20 were and are adequately described in its FDA-approved prescribing information, which was at
21 all times adequate and comported with applicable standards of care and law. Defendants deny
22 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23 87. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
28 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the

1 Complaint.

2 88. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
7 allegations in this paragraph of the Complaint.

8 89. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants state that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendants deny
14 any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
15 remaining allegations in this paragraph of the Complaint.

16 90. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Third Cause of Action:**

19 **Strict Products Liability – Defective Design or Manufacture**

20 91. Defendants incorporate by reference their responses to each paragraph of Plaintiffs’
21 Complaint as if fully set forth herein.

22 92. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
26 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
27 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
28 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Bextra® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
5 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
6 paragraph of the Complaint.

7 93. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants admit that Bextra® was expected to
14 reach consumers without substantial change from the time of sale. Defendants deny remaining
15 the allegations in this paragraph of the Complaint.

16 94. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
21 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

22 95. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
27 allegations in this paragraph of the Complaint.

28 96. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
5 allegations in this paragraph of the Complaint.

6 97. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants deny remaining the allegations in
8 this paragraph of the Complaint.

9 98. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
14 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
15 Complaint.

16 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 100. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 **Response to Fourth Cause of Action: Breach of Implied Warranty**

21 101. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
22 Complaint as if fully set forth herein.

23 102. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants admit, as indicated in the package
2 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
3 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
4 primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the
5 Complaint.

6 103. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
9 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
11 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
12 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
13 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
14 with their approval by the FDA. Defendants admit that they provided FDA-approved
15 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this
16 paragraph of the Complaint.

17 104. Defendants deny the allegations in this paragraph of the Complaint.

18 105. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
20 Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 106. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
24 Defendants state that Bextra® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
26 were and are adequately described in its FDA-approved prescribing information, which was at
27 all times adequate and comported with applicable standards of care and law. Defendants deny
28 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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1 107. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 108. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 109. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
11 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
12 and deny the remaining allegations in this paragraph of the Complaint.

13 110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Fifth Cause of Action: Breach of Express Warranty**

16 111. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
17 Complaint as if fully set forth herein.

18 112. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 113. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants admit that they provided FDA-approved prescribing information regarding

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1 Bextra®. Defendants deny any wrongful conduct and deny the remaining allegations in this
2 paragraph of the Complaint, including all subparts.

3 114. Defendants deny the allegations in this paragraph of the Complaint.

4 115. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 116. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 117. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants admit that they provided FDA-approved prescribing information regarding
19 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 118. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 119. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 120. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 121. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.
28

Response to Sixth Cause of Action: Common Law Fraud

122. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

124. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

126. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 127. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is deemed required. To the extent a response is deemed required,
6 Defendants admit that they had duties as are imposed by law but deny having breached such
7 duties. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
9 Defendants state that Bextra® was and is safe and effective when used in accordance with its
10 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
11 were and are adequately described in its FDA-approved prescribing information, which was at
12 all times adequate and comported with applicable standards of care and law. Defendants deny
13 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

14 128. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 129. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants state that Bextra® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
24 were and are adequately described in its FDA-approved prescribing information, which was at
25 all times adequate and comported with applicable standards of care and law. Defendants deny
26 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 130. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

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1 Defendants state that Bextra® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
3 were and are adequately described in its FDA-approved prescribing information, which was at
4 all times adequate and comported with applicable standards of care and law. Defendants deny
5 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

6 131. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 132. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Seventh Cause of Action: Fraudulent Misrepresentation and Concealment**

11 133. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
12 Complaint as if fully set forth herein.

13 134. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is deemed required. To the extent a response is deemed required,
15 Defendants admit that they had duties as are imposed by law but deny having breached such
16 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 135. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint, including all subparts.

27 136. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 137. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
10 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

11 138. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 139. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 140. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 141. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 142. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

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Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

143. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

144. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

145. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

146. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

147. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

148. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Eighth Cause of Action: Unjust Enrichment

149. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

150. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
4 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 151. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 152. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13 153. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants state that Bextra® was and is safe and effective when used in accordance with its
16 FDA-approved prescribing information. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 154. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
20 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
21 and deny the remaining allegations in this paragraph of the Complaint.

22 155. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Ninth Cause of Action: New York G.B.L. § 349**

25 156. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
26 Complaint as if fully set forth herein.

27 157. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

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1 158. Defendants deny any wrongful conduct and deny the remaining allegations in this
2 paragraph of the Complaint.

3 159. Defendants deny any wrongful conduct and deny the remaining allegations in this
4 paragraph of the Complaint.

5 160. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 161. Defendants deny any wrongful conduct and deny the remaining allegations in this
10 paragraph of the Complaint.

11 162. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
12 damage, and deny the remaining allegations in this paragraph of the Complaint.

13 163. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Prayer for Relief**

16 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
17 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
18 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

19 **III.**

20 **GENERAL DENIAL**

21 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’
22 Complaint that have not been previously admitted, denied, or explained.

23 **IV.**

24 **AFFIRMATIVE DEFENSES**

25 Defendants reserve the right to rely upon any of the following or additional defenses to
26 claims asserted by Plaintiffs to the extent that such defenses are supported by information
27 developed through discovery or evidence at trial. Defendants affirmatively show that:
28

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First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

1 **Eighth Defense**

2 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
3 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
4 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
5 liable in any way.

6 **Ninth Defense**

7 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
8 intervening causes for which Defendants cannot be liable.

9 **Tenth Defense**

10 10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were
11 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
12 of God.

13 **Eleventh Defense**

14 11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

15 **Twelfth Defense**

16 12. A manufacturer has no duty to warn patients or the general public of any risk,
17 contraindication, or adverse effect associated with the use of a prescription medical product.
18 Rather, the law requires that all such warnings and appropriate information be given to the
19 prescribing physician and the medical profession, which act as a “learned intermediary” in
20 determining the use of the product. Bextra® is a prescription medical product, available only
21 on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s
22 treating and prescribing physicians.

23 **Thirteenth Defense**

24 13. The product at issue was not in a defective condition or unreasonably dangerous at the
25 time it left the control of the manufacturer or seller.

26 **Fourteenth Defense**

27 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
28 for its intended use and the warnings and instructions accompanying Bextra® at the time of the

1 occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

2 **Fifteenth Defense**

3 15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the
4 Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable
5 standard of care.

6 **Sixteenth Defense**

7 16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the
8 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,
9 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or
10 persons acting on its behalf after the product left the control of Defendants.

11 **Seventeenth Defense**

12 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of
13 Defendants.

14 **Eighteenth Defense**

15 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent
16 conditions unrelated to Bextra®.

17 **Nineteenth Defense**

18 19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore,
19 the doctrine of assumption of the risk bars or diminishes any recovery.

20 **Twentieth Defense**

21 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
22 preempted in accordance with the Supremacy Clause of the United States Constitution and by
23 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

24 **Twenty-first Defense**

25 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
26 the subject pharmaceutical product at issue was subject to and received pre-market approval by
27 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

28

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Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitution of the State of Oklahoma, and the Constitution of the State of California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Oklahoma and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*

America, Inc. v. Gore, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were

1 independent of or far removed from Defendants' conduct.

2 **Forty-fifth Defense**

3 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
4 did not proximately cause injuries or damages to Plaintiffs.

5 **Forty-sixth Defense**

6 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs
7 did not incur any ascertainable loss as a result of Defendants' conduct.

8 **Forty-seventh Defense**

9 47. The claims asserted in the Complaint are barred, in whole or in part, because the
10 manufacturing, labeling, packaging, and any advertising of the product complied with the
11 applicable codes, standards and regulations established, adopted, promulgated or approved by
12 any applicable regulatory body, including but not limited to the United States, any state, and
13 any agency thereof.

14 **Forty-eighth Defense**

15 48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the
16 product labeling contained the information that Plaintiffs contends should have been provided.

17 **Forty-ninth Defense**

18 49. The claims asserted in the Complaint are barred because the utility of Bextra®
19 outweighed its risks.

20 **Fiftieth Defense**

21 50. Plaintiffs' damages, if any, are barred or limited by the payments received from
22 collateral sources.

23 **Fifty-first Defense**

24 51. Defendants' liability, if any, can only be determined after the percentages of
25 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if
26 any, are determined. Defendants seek an adjudication of the percentage of fault of the
27 claimants and each and every other person whose fault could have contributed to the alleged
28 injuries and damages, if any, of Plaintiffs.

1 **Fifty-second Defense**

2 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the
3 common law gives deference to discretionary actions by the United States Food and Drug
4 Administration under the Federal Food, Drug, and Cosmetic Act.

5 **Fifty-third Defense**

6 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
7 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
8 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'
9 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
10 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
11 and with the specific determinations by FDA specifying the language that should be used in the
12 labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the
13 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
14 United States.

15 **Fifty-fourth Defense**

16 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity
17 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

18 **Fifty-fifth Defense**

19 55. Defendants state on information and belief that the Complaint and each purported cause
20 of action contained therein is barred by the statutes of limitations contained in California Code
21 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
22 may apply.

23 **Fifty-sixth Defense**

24 56. Defendants state on information and belief that any injuries, losses, or damages suffered
25 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable
26 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against
27 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

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Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiffs' claim for non-economic damages is subject to the statutory limitations set forth in ORS 31.710.

Fifty-ninth Defense

59. Plaintiffs are not entitled to a private right of action under ORS 646.638.

Sixtieth Defense

60. Defendants' conduct complied with the orders or rules of, or a statute administered by a federal, state or local government agency, and, accordingly, Defendants are not liable under ORS 646.608.

Sixty-first Defense

61. Defendants are entitled to an award of attorney fees pursuant to ORS 646.638(3).

Sixty-second Defense

62. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;

1 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
2 than an amount which equals their proportionate share, if any, of the total fault or other liability
3 which proximately caused Plaintiffs' injuries and damages; and

4 6. That Defendants have such other and further relief as the Court deems appropriate.

5
6 November 15, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

November 15, 2007

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